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Press Office

Press release

Committee for Medicinal Products for Veterinary Use (CVMP) Meeting of 5-7 April 2011

CVMP opinions on veterinary medicinal products

The Committee adopted by majority a positive opinion for a marketing authorisation for **MS-H Vaccine** (*Mycoplasma synoviae* strain MS-H), from Pharmsure Ltd, a vaccine for the active immunisation of future broiler breeder chickens, future layer breeder chickens and future layer chickens to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae*.

The Committee adopted by consensus a final opinion, following a re-examination, for a type II variation application for **Masivet** (masitinib) from AB Science S.A; recommending the refusal of the proposed variation. The variation was to add atopic dermatitis as a new indication.

More information about the above mentioned veterinary medicines, including their full indications, can be found on the Agency's website.

The Committee adopted by consensus positive opinions for a type II variation applications for:

ProteqFlu-Te – extension of the duration of immunity against tetanus to 2 years and change of the vaccination scheme;

ProteqFlu – change of the vaccination scheme;

Previcox – the relief of the pain and inflammation associated with dental surgery in dogs as a new indication.

Renewals of marketing authorisation

The Committee adopted by consensus a positive opinion for the renewal of the marketing authorisation for **Convenia** (cefovecin) 80 mg/ml powder and solvent for solution for injection for dogs and cats. The Committee, having re-assessed the benefit-risk balance of this product, concluded that the quality, safety and efficacy continue to be appropriately demonstrated and, therefore, recommended the indefinite renewal of the marketing authorisation.

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Community referrals and related procedures

The Committee started a procedure under Article 35 of Directive 2001/82/EC for **all veterinary medicinal products containing systemically administered (parenteral and oral) 3rd and 4th generation cephalosporins** and intended for use in food producing species. The matter was referred to the CVMP by the European Commission in order to consider the inclusion of prudent use advice for these antimicrobials and to address the risk associated with potential misuse in poultry and the need for specific measures, in particular the need for warning sentences in the product literature.

The Committee concluded the procedure for **Combimox Lactating Cow Intramammary Suspension** (amoxicillin, clavulanic acid and prednisolone) from Norbrook Laboratories Ltd. The application was referred to CVMP for arbitration under Article 33(4) of Directive 2001/82/EC by the United Kingdom, acting as the reference Member State in a mutual recognition procedure, due to concerns raised by Ireland on the basis that a failure to demonstrate equivalence with the reference product could lead to a potential serious risk to human and animal health. The Committee adopted by majority an opinion concluding that it was not possible to establish a positive benefit-risk balance and recommending that the marketing authorisation should not be granted in the concerned Member State, Ireland, and that the marketing authorisation in the reference Member State, the United Kingdom, should be suspended.

The Committee concluded the procedure for **Nisamox Lactating Cow Intramammary Suspension** (amoxicillin, clavulanic acid and prednisolone) from Norbrook Laboratories Ltd. The application was referred to CVMP for arbitration under Article 33(4) of Directive 2001/82/EC by the United Kingdom, acting as the reference Member State in a mutual recognition procedure, due to concerns raised by the Netherlands on the basis that a failure to demonstrate equivalence with the reference product could lead to a potential serious risk to human and animal health. The Committee adopted by majority an opinion concluding that it was not possible to establish a positive benefit-risk balance and recommending that the marketing authorisation should not be granted in the concerned Member State, the Netherlands, and that the marketing authorisation in the reference Member State, the United Kingdom, should be suspended.

The Committee concluded the procedure for **Combisyn Lactating Cow Intramammary Suspension** (amoxicillin, clavulanic acid and prednisolone) from Norbrook Laboratories Ltd. The application was referred to CVMP for arbitration under Article 33(4) of Directive 2001/82/EC by the United Kingdom, acting as the reference Member State in a mutual recognition procedure, due to concerns raised by France on the basis that a failure to demonstrate equivalence with the reference product could lead to a potential serious risk to human and animal health. The Committee adopted by majority an opinion concluding that it was not possible to establish a positive benefit-risk balance and recommending that the marketing authorisation should not be granted in the concerned Member States, Austria, Belgium, Denmark, Finland, France, Portugal and Spain, and that the marketing authorisation in the reference Member State, the United Kingdom, should be suspended.

Maximum Residue Limits

The Committee adopted by consensus an opinion recommending the extrapolation of the existing MRL status for **azamethiphos** to fin fish. Azamethiphos is currently included in table 1 of the annex of Commission Regulation (EU) No 37/2010 for Salmonidae with a “No MRL required” status.

Pharmacovigilance

The Committee reviewed the PSURs for **Draxxin**, **Duvaxyn WNV**, **Easotic**, **Improvac**, **Leucofeligen FeLV/RCP**, **Masivet**, **Palladia**, **Posatex** and **PRILACTONE** and concluded that no further action or changes to their product literature were required.

Concept papers, guidelines and SOPs

Efficacy

The Committee adopted a revised Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00-Rev.3) following the close of a second round of public consultation. The revised guideline provides clearer guidance to applicants on how to conduct bioequivalence studies for systemically available veterinary medicinal products, and also provides details on exceptions to those requirements (biowaivers).

The document and the overview of comments received during public consultation will be published on the Agency's website.

The Committee adopted a Concept paper on the revision of the CVMP Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/760764/2010) for a 3-month period of public consultation. A revision of the current guideline is proposed, as clearer guidance is considered necessary with regard to efficacy testing of antimicrobials and prudent use in view of the risk of development of resistance.

The document will be published on the Agency's website.

Procedural announcement

The European Commission has recently announced a change in the operation of the procedures for variations to a marketing authorisation in the form of a procedural note. The text of the note is replicated below:

"Procedural note concerning the guideline on the operation of the procedures laid down in chapters II, III, and IV of COMMISSION REGULATION (EC) 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products

Section 2.3.5 of the Guideline on the operation of the procedures laid down in Chapters II, III and IV of Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products provides that major variations of Type II that do not require a Commission decision amending the relevant marketing authorisation may be implemented after the marketing authorisation holder has been informed by the Commission. As from 1 May 2011, the task of informing marketing authorisation holders that these variations may be implemented is delegated to the European Medicines Agency."

Notes

1. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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